Congress of the United States
Washington, DC 20515

May 24, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

On February 9, 2018 President Donald Trump signed into law H.R. 1892, the Bipartisan Budget Act of 2018 (now Public Act 115-123). Title III of the new law, Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act, includes a provision to expand Medicare coverage for telestroke services. This is an important development that allows specialists to deliver more timely treatment through telemedicine for patients presenting with stroke.

Within that Title, Section 50325 of the law is an expansion of Medicare's telemedicine reimbursement policy to include mobile stroke units (MSUs):

> *SSA 50302(b)(2) ''(B) INCLUSION OF CERTAIN SITES.—With respect to telehealth services described in subparagraph (A), the term 'originating site' shall include any hospital (as defined in section 1861(e)) or critical access hospital (as defined in section 1861(mm)(1)),* ***any mobile stroke unit (as defined by the Secretary)****, or any other site determined appropriate by the Secretary, at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system.* [Emphasis added.]

As you develop regulations to implement the law, we encourage the Centers for Medicare and Medicaid Services (CMS) to draft regulations that operationalize Section 50325 and fully recognize the pillars on which MSUs provide critical pre-hospital stroke care to Medicare beneficiaries: evaluation, diagnosis and treatment. MSUs help to expand access to timely care for stroke victims in the pre-hospital setting and hold great promise for improving both patient outcomes and the cost-effectiveness of the care provided to Medicare beneficiaries suffering from stroke.

Stroke is a leading cost-driver for the Medicare program. It is the 5th leading cause of death in the U.S.[1], with 60 percent of all stroke deaths occurring outside of an acute care hospital[2]. Stroke is also a leading cause of serious long-term disability in the U.S., reducing mobility in more than half of all stroke survivors age 65 and over[3]. Ultimately, stroke costs the U.S. economy an estimated $34 billion annually[4].

Stroke also has a significant impact on the Medicare program[5]. The incidence of stroke in the U.S. is 500 percent higher among adults 65 or older compared to those ages 18-44[6]. Stroke is already among the top 10 most expensive conditions billed to Medicare. In fact, non-nursing home costs due

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[1] *Heart Disease and Stroke Statistics - 2017 Update: A Report from the American Heart Association*; January 25, 2017.
[2] *Ibid.*
[3] Ibid.
[4] Ibid.
[5] *Implementing a Mobile Stroke Unit Program in the United States: Why, How and How Much?* JAMA Neurology, Volume 72, Number 2; February 2015.
[6] *Heart Disease and Stroke Statistics - 2017 Update: A Report from the American Heart Association*, January 25, 2017.

to stroke alone consume more than 10 percent of Medicare's overall budget[7]. Looking ahead to 2030, the incidence of stroke in the U.S. is expected to increase 25 percent while the total costs (both direct and indirect) due to stroke care are projected to increase 160 percent[8]. This anticipated growth in the incidence of and costs attributable to stroke will undoubtedly have a significant impact on Medicare.

With stroke, every second counts. Nearly 2 million brain cells die every minute after a stroke's onset, so ensuring that patients receive the most appropriate care as quickly as possible can significantly help improve outcomes, prevent long-term disability and lower the long-term costs of stroke[9].

Nearly 90 percent of all strokes are ischemic strokes in which blood flow to the brain is blocked and without timely treatment can lead to death or disability[10]. Tissue plasminogen activator, or "tPA," is globally recommended for ischemic strokes[11]. Studies show that for the use of tPA helps improve patient outcomes and reduce both the short-term and long-term costs due to stroke. For the short-term, the administration of tPA leads to a lower length of hospital stay for stroke victims.[12] Use of tPA also helps reduce long-term disability which, in turn, lowers the long-term costs due to stroke[13].

MSUs are dedicated emergency vehicles equipped with trained clinicians who provide patients that may be having a stroke with improved access to the most advanced pre-hospital stroke treatment and technology currently available. These units offer a new and innovative health care delivery approach that hold great promise to significantly improve access to timely and quality stroke care; and, provide the Medicare program with a real cost savings for both the short-term and over the long-term. Specifically, MSUs use Computed Tomography (CT) mobile imaging, telemedicine and other cutting-edge technology, all of which helps improve outcomes for and lower the mortality rate for stoke victims. As of this writing, there are currently nine known health care systems with MSUs in operation in the U.S. today.

MSUs can significantly increase timely access to pre-hospital stroke care, including the administration of tPA, by ensuring the administration of the clot-busting drug in the pre-hospital setting prior to arrival at the hospital emergency department. Studies show that MSUs effectively reduce the overall time required to administer tPA to stroke victims[1415]. MSUs also help bring the most severe stroke cases to the appropriate hospital quickly and, in turn, offer patients the best chance of recovery. For example, MSUs also allow for the administration of thrombectomy or endovascular clot removal.

Ultimately, MSUs help improve outcomes for stroke victims, but also lower the costs of caring by helping to triage patients to the appropriate hospital (e.g., comprehensive vs. primary stroke centers); reduce inpatient hospital costs, readmissions and use of post-acute care; improve medication compliance; and, increase patient satisfaction. This is especially important because, and as noted above, the incidence of stroke and the associated costs of treating stroke victims continue to increase

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[7] *Implementing a Mobile Stroke Unit Program in the United States: Why, How and How Much?* JAMA Neurology, Volume 72, Number 2; February 2015.

[8] *Forecasting the Future of Cardiovascular Disease in the United States: A Policy Statement from the American Heart Association*; American Health Association Journals; Paul A. Heidenrich, MD, et. al.; March 1, 2011.

[9] http://www.stroke.org/sites/default/files/resources/NSA_%20FactSheet_Stroke_101_2014.pdf

[10] *Heart Disease and Stroke Statistics - 2017 Update: A Report from the American Heart Association*, January 25, 2017.

[11] http://www.strokeassociation.org/idc/groups/stroke-public/@wcm/@hcm/@gwtg/documents/downloadable/ucm_430859.pdf

[12] https://www.sciencedaily.com/releases/2014/02/140212183526.htm

[13] *Time to Treatment with Intravenous Tissue Plasminogen Activator and Outcome from Acute Ischemic Stroke.* Journal of the American Medical Association; Jeffrey Saver, M.D. et. al; 2488-2480: (23) 309; 2013.

[14] *Benefits of Stroke Treatment Using a Mobile Stroke Unit Compared with Standard Management*; Ritvij Bowry, M.D., et. al.; Stroke; September 22, 2015.

[15] *Implementing a Mobile Stroke Unit Program in the United States: Why, How and How Much*; Suja S. Rajan, Ph.D. et. al.; JAMA Neurology, Vol. 72, No. 2; February 2015.

– especially for the Medicare program. Note also that because of the work MSUs perform in the field, some patients are able to avoid a trip to the hospital emergency department and proceed straight to the catheterization laboratory, stroke unit or intensive care unit. This also can amount to a considerable cost savings.

We urge CMS to develop regulations that implement Section 50325 of P.L. 115-123 and ensure appropriate reimbursement from Medicare for the highly-specialized, critical care stroke-related services provided to beneficiaries via an MSU. Services performed by an MSU in the diagnosis, evaluation and treatment of an acute stroke as defined by Section 50325 include (but are not limited to):

- A tele-neurology exam by a consulting neurologist who evaluates the patient in real time in conjunction with the paramedics on board the unit or an in-person physical examination by a physician or a nurse practitioner on board the unit.

- Point-of-care laboratory testing to determine critical factors, such as serum glucose and international normalized ratio (INR, or "clotting") results.

- A computed tomography (CT) and CT angiography scan (e.g., used to rule out a hemorrhagic stroke and identify patients with large vessel occlusions in need for mechanical thrombectomy).

- A wireless connection to allow for the immediate transmittal of CT images to the hospital-based radiologist for interpretation.

- Administration of clot-busting (e.g., tPA), coagulation (e.g., K-centra) and intravenous anti-hypertensive (e.g., labetalol, nicardipine) drugs.

- Subsequent transport of the patient to an appropriate-level hospital emergency department for follow-up care.

Attached please find as Appendix I a detailed list of the Diagnosis-Related Group (DRG) classifications recognizing the stroke and stroke-related care provided by MSUs. We urge CMS to ensure that these services are recognized and reimbursed by Medicare, as they are each necessary in the diagnosis, evaluation and treatment of an acute stroke as defined in Section 50325.

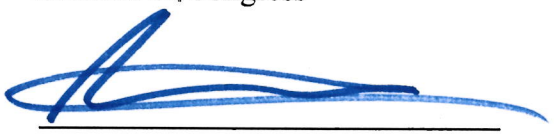
We thank you for your leadership and consideration of our request for Medicare to recognize and reimburse for the care provided by MSUs. The incidence of stroke is already a leading cause of death, disability and rising health care costs in the United States - especially among Medicare beneficiaries. Moreover, the incidence of stroke, and its associated costs, will only continue to increase for the foreseeable future. MSUs offer a promising technology to reduce the time between stroke onset and critical clinical intervention and, in turn, manage stroke care in the U.S. that will lead to improved patient outcomes and reduced costs for the Medicare program.

Sincerely,

PETER J. ROSKAM
Member of Congress

RADNY HULTGREN
Member of Congress

TIM RYAN
Member of Congress



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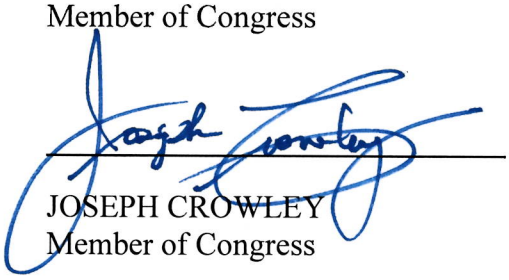

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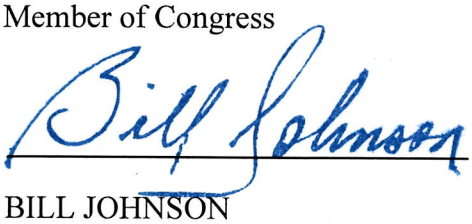

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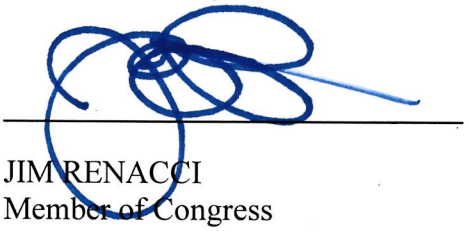

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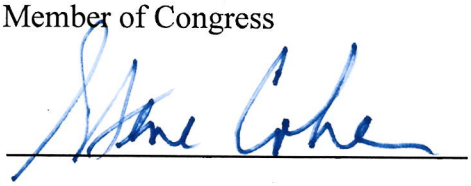

STEVE COHEN
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MIKE COFFMAN
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